UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No.: 0:22-cv-61192-WPD

SCILEX PHARMACEUTICALS INC., ITOCHU CHEMICAL FRONTIER CORPORATION, AND OISHI KOSEIDO CO., LTD.,

Plaintiffs,

v.

AVEVA DRUG DELIVERY SYSTEMS, INC.,

Defendant.

PLAINTIFFS' DAUBERT MOTION TO EXCLUDE CERTAIN OPINIONS OF DEFENDANT'S EXPERT DR. MAUREEN DONOVAN AND INCORPORATED MEMORANDUM OF LAW

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I. INTRODUCTION

Scilex Pharmaceuticals Inc., ITOCHU CHEMICAL FRONTIER Corporation, and Oishi Koseido Co., Ltd. (collectively, "Plaintiffs") file this motion to exclude certain opinions directed to the breadth of the claims and alleged supporting calculations from the reports of Defendant Aveva Drug Delivery Systems, Inc. ("Aveva")'s expert, Dr. Maureen Donovan.

In her opening expert report ("Opening Report"), Dr. Donovan opines that after evaluating the *Wands* factors, U.S. Patent Nos. 9,283,174 ("'174 patent"), 9,925,264 ("'264 patent"), and 9,931,403 ("'403 patent") (collectively referred to as the "Asserted Patents") are invalid for lack of enablement. However, Dr. Donovan's opinions are based on arbitrary assumptions and misleading calculations at least with respect to *Wands* factor (1) the breadth of the asserted claims. Accordingly, this motion seeks to exclude the opinions of Dr. Donovan related to the breadth of the asserted claims because they are unreliable and do not assist the trier of fact, encompassed by paragraphs 297-334 and Appendices D and E of her Opening and Corrected Opening Report, and paragraph 74 of her Reply and Corrected Reply Report. (Ex. 1 (Opening Report); Ex. 2 (Corrected Opening Report); Ex. 3 (Reply Report); Ex. 4 (Corrected Reply Report).)[1]

II. FACTUAL BACKGROUND

Plaintiff Oishi developed a non-aqueous, topical lidocaine patch called ZTlido® to address the poor adhesion and permeability issues of aqueous and non-aqueous lidocaine patches that existed at the time. The high concentration of lidocaine in the existing patches presented serious safety issues, while lower concentration non-aqueous patches did not stably release lidocaine over long periods of time. Oishi developed and patented a novel non-aqueous lidocaine patch

[1] Dr. Donovan's Expert Reports were originally marked Highly Confidential when served, but the parties conferred and the excerpted portions in Exhibits 1-4 attached to this motion do not contain either parties' confidential information.

composition that contained lower amounts of lidocaine while maintaining efficacy overcoming these issues. Scilex is the exclusive licensee of Oishi's patented technology, which is embodied in Scilex's prescription lidocaine topical patch, ZTlido®. Scilex is the holder of New Drug Application No. 207962 for ZTlido® and markets ZTlido® in the United States.

The Asserted Patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") in relation to ZTlido®. The patents share a common specification and each expires on May 10, 2031. Each Asserted Patent includes a single independent claim (claim 1) which recites a "non-aqueous patch comprising 0.5 to 7 mass % lidocaine," and a "dissolving agent" consisting, or consisting essentially of, "an organic acid and a polyalcohol, which are contained in a plaster," "wherein the amount of lidocaine . . . is 0.5 to 5 % mass % of dissolving agent relative to 1 mass % of lidocaine." (Ex. 5 ('174 Patent) at cl. 1; Ex. 6 ('403 Patent) at cl. 1; Ex. 7 ('264 Patent) at cl. 1.) Notably, none of the Asserted Patents claim the method of manufacturing the patch.

Seeking to benefit from Plaintiffs' significant investment in developing ZTlido®, Aveva submitted an ANDA seeking FDA approval to market a generic copy of ZTlido®. As part of Aveva's submission, it filed a paragraph IV certification[2] alleging that the claims of the Asserted Patents are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Defendants' ANDA Product. After receiving notice of ANDA filing from Aveva, Plaintiffs filed the instant lawsuit for infringement of claims 1-4, 6-10, and 14-16 of the '174 patent, claims 1-4, 6-10, and 14-15 of the '403 patent, and claims 1-4, 6-10, and 12-16 of the '264 patent

[2] A paragraph IV certification is required by Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. §355(b)(2)(A)(iv) and includes a generic drug applicant's opinion on the patents listed for the brand-name drug in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

(collectively the "Asserted Claims"). Aveva contends that its proposed product does not infringe any of the Asserted Claims and that the Asserted Claims are invalid for lack of enablement.

On July 11, 2023, Aveva submitted Dr. Donovan's Opening Report on the issue of validity in which she concludes, relying on inaccurate calculations, that the Asserted Claims are not enabled because it would require undue experimentation to practice the claims. (*See generally* Ex. 2 (Corrected Opening Report) at ¶¶ 264-419.) Dr. Donovan's enablement opinions are premised on "exemplary" calculations which she asserts confirm the breadth of the Asserted Claims and weigh in favor of finding for undue experimentation. (*See* Ex. 2 (Corrected Opening Report) at ¶¶ 297-334, Appendices D and E; Ex. 4 (Corrected Reply Report) at ¶ 74.) In particular, Dr. Donovan relies on her calculations to argue that the claims of the Asserted Patents are extremely broad, and it would require undue experimentation to practice the full scope of the claims. Dr. Donovan's calculations are fundamentally flawed such that they misrepresent the scope of the claims, including incorrectly indicating that the scope of dependent claims are broader than the independent claim from which they depend. *See infra* Section (IV)(A)(1)(a). Furthermore, Dr. Donovan's calculations rely on a number of unsupported, arbitrary assumptions that render the results both unreliable and uninformative. Finally, Dr. Donovan failed to reliably follow her own methodology and included numerous calculations that are mathematically incorrect in her Opening Report. (*See* Ex. 2 (Corrected Opening Report) at Appendices D and E.)

On February 2, 2024, the Plaintiffs served the Rebuttal Expert Report of John J. Koleng, Ph.D ("Koleng Rebuttal Report") identifying the fundamental flaws and inaccuracies in the calculations on which Dr. Donovan's opinions are predicated. (*See* Exhibit 10 (Koleng Rebuttal Report).)

On February 23, 2024, Defendant served Dr. Donovan's Reply Report. In her Reply Report Dr. Donovan noted the flaws and inaccuracies identified by Dr. Koleng but failed to correct her calculations or address the fundamental flaws in the assumptions on which her calculations are premised. (*See* Exhibit 4 (Corrected Reply Report at ¶ 48).) Only after Dr. Donovan's deposition on April 2, 2024, where counsel for Plaintiffs questioned Dr. Donovan with respect to her failure to address these inaccuracies, did the Defendant serve a Corrected Opening Report. (*See* Ex. 2 (Corrected Opening Report).) While the Corrected Opening Report addresses several inaccuracies in Dr. Donovan's Opening Report it does not address the fundamental flaws in the assumptions on which her calculations are based and still contains inaccurate calculations.

III. LEGAL STANDARDS

Federal Rule of Evidence 702, as explained in *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579 (1993) and its progeny, governs the admission of expert testimony. Under Rule 702, expert testimony is permitted by "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education" if four criteria are met: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702. The Supreme Court in *Daubert* interpreted Rule 702 to require that the district court act as a "gatekeeper" of expert testimony. *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291-92 (11th Cir. 2005) .

The Eleventh Circuit has set forth a three-part inquiry for evaluation of proposed expert testimony: "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue." *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998). The 11th Circuit refers to these requirements as the "qualifications," "reliability," and "helpfulness" prongs. *King v. Cessna Aircraft Co.*, No. 03-20482-CIV, 2010 WL 1980861, at *1 (S.D. Fla. May 18, 2010) (citing *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004)). The party seeking to introduce the expert at trial bears the burden of establishing her qualifications, and the reliability and helpfulness of her opinions. *See Frazier*, 387 F.3d at 1260.

In determining the reliability of a scientific expert opinion, the Eleventh Circuit considers the following to the extent possible: "(1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.,* 326 F.3d 1333, 1341 (11th Cir. 2003) (citing *McCorvey v. Baxter Healthcare Corp.,* 298 F.3d 1253, 1256 (11th Cir. 2002)).

The requirement that the expert testimony be helpful to the trier of fact essentially requires the testimony to be relevant to the issues. "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (citation omitted).

With respect to enablement, a patent must provide a sufficient description of the claimed invention to permit or enable a person of ordinary skill in the art to make and use the claimed invention. *See* 35 U.S.C § 112; *Amgen Inc. v. Sanofi*, 598 U.S. 594, 605 (2023) . This requirement is met when, at the time of filing the application, one skilled in the art, having read the specification, could practice the invention without "undue experimentation." *See In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988) . To determine whether the amount of experimentation is undue, the Federal Circuit articulated in eight ("*Wands*") factors that may be considered in the analysis: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737. While these factors are a useful methodology for determining enablement, they are not mandatory. *See Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) . While experimentation must not be undue, a reasonable amount of routine experimentation required to practice a claimed invention does not violate the enablement requirement. *See id.*

IV. ARGUMENT

An expert's opinion is considered reliable if it is based on valid, reliable knowledge. *Daubert*, 509 U.S. at 589–90. However, expert opinions are inadmissible if they are the product of unreliable principles and methods or if they rely on incorrect facts or data. *Id.* at 591–95.

Dr. Donovan's analysis is unreliable for multiple reasons. Her calculations of "potential formulations" for the asserted claims are unreliable and unhelpful due to critical inaccuracies and unsupported assumptions, resulting in paradoxical conclusions and persistent errors even after attempted corrections. Dr. Donovan's analysis of claimed concentration ranges lacks basis and relevance, as it overlooks practical considerations and fails to align with the enablement requirement. Furthermore, her inclusion of unclaimed limitations introduces unnecessary complexity and deviates from fundamental principles of enablement. Overall, Dr. Donovan's methodology is unreliable and unhelpful, and thus, the calculations and opinions relying on those calculations regarding the breadth of the claims and quantity of experimentation must be excluded.

A. Dr. Donovan's Analysis of the Breadth of the Asserted Claims is Fundamentally Flawed

1. Dr. Donovan's Calculations of "Potential Formulations" are Unrelated to Claim Scope and Should be Excluded as Unreliable and Unhelpful

Dr. Donovan's Opening Report and Corrected Opening Report present a series of combination calculations that she asserts "confirm the breadth of the Asserted Claims." (*See* Ex. 1 (Opening Report) at ¶ 299; Ex. 2 (Corrected Opening Report) at ¶ 299.) For the reasons that follow, Dr. Donovan's calculations are not representative of the breadth of the claims and are built upon a series of inaccurate and unsupported assumptions. (*See id.* at ¶ 300.) Accordingly, the calculations presented in Appendix E and methodology presented in Appendix D of Dr. Donavan's Opening Report and Corrected Opening Report, as well as her opinions in ¶¶ 297-334 of her Opening and Corrected Opening Report, and ¶ 74 of her Reply and Corrected Reply Report that depend on these calculations, are unreliable and unhelpful to the trier of fact, and should be excluded.

Dr. Donovan performs a series of calculations that she asserts represent the number of "potential formulations" each Asserted Claim encompasses. (*See* Exs. 1, 2 (Opening and

Corrected Opening Report) at Appendix D.) To arrive at the purported number of "potential formulations" for each claim, Dr. Donovan multiplies the number of options for various variables which she asserts a person of ordinary skill ("POSA") would consider in relation to the claim. (*See* Exs. 1, 2 (Opening and Corrected Opening Report) at Appendix D.) For example, Dr. Donovan concludes that claim 1 of the '174 patent encompasses 1,111,176,000 "potential formulations." Claim 1 of the '174 patent recites:

> A non-aqueous patch comprising 0.5 to 7 mass % lidocaine and/or its reactant, and a dissolving agent consisting of an organic acid and a polyalcohol, which are contained in a plaster, wherein the amount of lidocaine and/or its reactant is 0.1 to 1 mg/cm^2 of the plaster, and wherein the proportion of dissolving agent to lidocaine and/or its reactant is 0.5 to 5 mass % of dissolving agent relative to 1 mass % of lidocaine and/or its reactant.

(Ex. 5 ('174 patent), cl. 1.) To reach the supposed 1,111,176,000 "potential formulations" encompassed by claim 1 of the '174 patent, Dr. Donovan assumes that a POSA would consider (1) 5 methods of manufacture; (2) 66 different lidocaine percentages; (3) 4 different forms of the lidocaine drug substance, including lidocaine free base, an *in situ* salt, complex and a degradant; (4) 30 organic acids; (5) 61 polyalcohols; (6) 10 concentrations of lidocaine per cm^2 of plaster; and (7) 46 different ratios of dissolving agent to lidocaine. (*See* Ex. 2 (Corrected Opening Report), Appendix D at 2–3.) Dr. Donovan then multiplies the number of options for each variable to arrive at the number of "potential formulations" encompassed by a claim (e.g., 5*66*4*30*61*10*46 = 1,111,176,000). (*See* Ex. 2 (Corrected Opening Report), Appendix D at 3.)

For the dependent Asserted Claims, Dr. Donovan multiplies the number of "potential formulations" she has calculated for the independent claim by the number of options she asserts a POSA would consider in relation to the dependent claim limitation. For example, Dr. Donovan asserts that a POSA would consider 196 different amounts of lidocaine in relation to dependent claim 15 of the '174 patent which recites "[t]he non-aqueous patch according to claim 1, wherein

the amount of lidocaine and/or its reactant is 196 mg or less." (*See* Ex. 2 (Corrected Opening Report), Appendix D at 3–5.) Thus, to calculate the number of "potential formulations" encompassed by claim 15 of the '174 patent Dr. Donovan multiplies the 1,111,176,000 "potential formulations" for claim 1 by the 196 different amounts of lidocaine a POSA would consider in relation to the limitation of claim 15 to arrive at an even larger total number of 217,790,496,000 "potential formulations" for claim 15. (*See* Ex. 2 (Corrected Opening Report), Appendix E at 4.)

a. The number of "potential formulations" according to Dr. Donovan's calculations is unreliable because it is unrelated to the breadth of the claims

Dr. Donovan's calculations defy logic and fail to adhere to established principles of patent law. For example, according to Dr. Donovan's calculations (even after attempted correction), dependent claim 15, which recites more limitations than claim 1, and is therefore narrower than claim 1, would purportedly be broader (i.e., encompasses more "potential formulations") than independent claim 1, reciting fewer limitations, contradicting fundamental principles of claim dependency. (*See* Ex. 2 (Corrected Opening Report) at Appendix E (Calculation 1 embodies independent claim 1 of the '174 patent and provides 1,111,176,000 possible formulations, whereas Calculation 33 embodies dependent claim 15 of the same patent and provides 217,790,496,000 possible formulations)); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("[u]nder the doctrine of claim differentiation, dependent claims are presumed to be of narrower scope than the independent claims from which they depend."). For example, claim 15 of the '174 patent depends from claim 1 and, as such, dependant claim 15 under principles of claim drafting, is narrower than claim 1 with respect to the amount of lidocaine. *See Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006) ("[T]he statute stresses that a dependent claim must add a limitation to those recited in the independent claim. *See* 35 U.S.C. § 112, ¶ 4 (2000) ('[A] claim in dependent form shall contain a

reference to a claim previously set forth and then specify a further limitation of the subject matter claimed.')").

In fact, Dr. Donovan never offers the opinion that claim 15 is an improper dependent claim with a broader scope than claim 1. If Dr. Donovan's calculations were truly related to the scope of the claims, then the number of "potential formulations" for a dependent claim will be less than the independent claim from which it depends—and in no case should the number of "potential formulations" for a dependent claim be greater than the independent claim from which it depends. However, Dr. Donovan's method of calculating the number of "potential formulations" encompassed by the Asserted Claims consistently results in dependent claims encompassing more "potential formulations" than the independent claim from which they depend. For example, as described above, claim 15 of the '174 patent depends from claim 1 and is narrower than claim 1, yet according to Dr. Donovan's calculations dependent claim 15 encompasses 217,790,496,000 "potential formulations" as compared to independent claim 1 which encompasses 1,111,176,000 "potential formulations." This same lack of logic is also fatal for Dr. Donovan's calculations directed to the scope of other dependent claims in all 3 Asserted Patents. Dr. Donovan nonsensically claims dependent claims 7 (33,557,515,200 "potential formulations"), 8 (24,668,107,200 "potential formulations"), 10 (4,000,233,600 "potential formulations"), 12 (16,667,640,000 "potential formulations"), 13 (16,667,640,000 "potential formulations"), and 14 (7,778,232,000 "potential formulations") of the '174 patent, all of which ultimately depend from claim 1, encompass far more "potential formulations" than the broader scope of claim 1. (*See* Ex. 2 (Corrected Opening Report) at Appendix E ('174 Patent Calculations).)

Likewise, In the case of the '264 patent, Dr. Donovan has stated that independent claim 1 encompasses 277,794,000 "potential formulations," while dependent claims 7 (8,389,378,800

"potential formulations"), 8 (6,167,026,800 "potential formulations"), 10 (5,000,292,000 "potential formulations"), 12 (75,004,380,000 "potential formulations"), 13 (4,166,910,000 "potential formulations"), and 14 (1,944,558,000 "potential formulations") all depend on claim 1 and encompass a much broader scope of "potential formulations." (*See* Ex. 2 (Corrected Opening Report) at Appendix E ('264 Patent Calculations).) Lastly, with regard to the '403 patent, Dr. Donovan asserts that independent claim 1 encompasses 277,294,000 "potential formulations," while dependent claims 8 (6,167,026,800 "potential formulations"), 10 (5,000,292,000 "potential formulations"), 12 (833,382,000 "potential formulations"), 13 (4,166,910,000 "potential formulations"), and 14 (388,911,600 "potential formulations") all depend on claim 1 and encompass a much broader scope of "potential formulations." (*See* Ex. 2 (Corrected Opening Report) at Appendix E ('403 Patent Calculations).)"

Thus, according to Dr. Donovan's calculations, a claim with more limitations nonsensically includes a greater number of potential formulations and broader claim scope than the independent claim from which they depend.

This assertion contradicts well-established legal principles wherein it is widely accepted that an independent claim is inherently broader than a dependent claim. However, during her deposition, when questioned about this basic legal concept, Dr. Donovan failed to concede this established principle and even stated that her calculations do not confirm the breadth of the claims. (*See* Ex. 8 (Donovan Tr.) at 246:19-249:9, 254:23-25 ("Again, the numbers that are calculated are not a direct reflection of the breadth of the claim.")). Such a refusal to acknowledge fundamental legal principles, let alone apply them, calls into question the reliability of her testimony and the validity of her calculations.

Based on these erroneous calculations Dr. Donovan asserts that "even using conservative assumptions, the Asserted Claims are directed to a vast scope, encompassing millions and billions of potential formulations for claims directed to a dissolving agent consisting of an organic acid and a polyalcohol and over a hundred thousand for claims directed to a dissolving agent consisting of isostearic acid and dipropylene glycol." (Ex. 2 (Corrected Opening Report) at ¶ 333.) Dr. Donovan goes on to conclude based on her calculations that "the *Wands* factor concerning the breadth of the claims weighs in favor of a finding of undue experimentation." *Id.* at ¶ 334.

Because Dr. Donovan's calculations of the "potential formulations" encompassed by the Asserted Claims produce results that are divorced from the actual scope of the Asserted Claims, the method is not a reliable indication of the breadth of the Asserted Claims and does not assist the trier of fact in forming conclusions based on the facts of the case. Instead, her methodology only adds unnecessary confusion and complexity to the analysis. The calculations in Appendix D and E of Dr. Donovan's Opening and Corrected Opening Reports, as well as her opinions in ¶¶ 297-334 that depend on these calculations, and ¶ 74 of her Reply and Corrected Reply Report, should be excluded as they are deemed unreliable and unhelpful to the trier of fact. (Exs. 1, 2 (Opening and Corrected Opening Report) at ¶¶ 297-334, Appendix D, Appendix E; Exs. 3, 4 (Reply and Corrected Reply Report) at ¶ 74.)

b. Numerous Mathematical Errors and Inconsistencies Remain in Dr. Donovan's Corrected Opening Report

There are numerous errors throughout Dr. Donovan's calculations—errors which were not identified or corrected by Dr. Donovan until after her deposition. (*See* Ex. 2 (Corrected Opening Report) at Appendix E (Calculations 13-23, 50-58, 65-67, 71-73, 88-96, 100-102, 106-111.) Dr. Donovan's calculations should not be relied upon for the additional reason that, despite providing

a "Corrected" Opening Report following her deposition, numerous mathematical errors and inconsistencies remain.

Dr. Donovan's Corrected Opening Report contains persistent errors and inconsistencies, even after attempted corrections. For example, in her Opening Report, even applying her flawed logic, Dr. Donovan miscounted the number of discrete concentrations of lidocaine between 0.5 to 7% at increments of 0.1 initially stating there were 75 options within this range when there are actually 66 0.1 increments between 0.5 to 7. Despite acknowledging this error and revising her report, Dr. Donovan failed to used this "corrected" value in her other calculations and instead continued to use the incorrect 75 value throughout the entirety of her Corrected Opening Report and continues to cite the incorrect figure of 75 in numerous instances. (*Compare* Ex. 1 (Opening Report) at ¶¶ 278, 284, 287, 288, 291, 292, 294, 375 *with* Ex. 2 (Corrected Opening Report) at ¶¶ 278, 284, 287, 288, 291, 292, 294, 375.) That is, Dr. Donavan's opinions are still based on erroneous calculations despite attempting to correct them.

In addition, Appendix B to Dr. Donovan's Opening Expert Report consists of "consolidated" lists of organic acids and polyalcohols from the 2009 Handbook of Pharmaceutical Excipients and/or 2011 Pharmacopeia National Formulary that Dr. Donovan believes are relevant to her analysis. Dr. Donovan's original Appendix B contained multiple duplicates of excipients, thereby inflating the total count of both relevant organic acids and polyalcohols, according to Dr. Donovan. (*See* Ex. 1 (Opening Report) at Appendix B.) For example, the list of Organic Acids in Appendix B lists both Fumaric acid and Lactobionic acid twice, and the list of Organic Polyols lists the following excipients twice: Glyceryl monooleate, Glyceryl monostearate, Tartaric acid, Triethanolamine, and Erythritol. (*See id.*) Accordingly, the number of Organic Acids should have been 30 instead of 32, and the number of Polyols should have been 61 instead of 66. Dr. Koleng

addressed these inaccuracies in his rebuttal to Dr. Donovan and Aveva's Opening Report. (*See* Ex. 10 (Koleng Rebuttal Report) at ¶ 178). Instead of addressing the inaccuracies and amending her initial report, Dr. Donovan chose to put the onus back on Dr. Koleng to identify the individual flaws in her report with specificity. (Ex. 3 (Reply Report) at ¶ 48 ("Yet, he does not identify which of the 'compounds' are duplicated.").) Although Appendix B was "corrected" after it was brought to Dr. Donovan's attention during her deposition, where she described these flaws as careless additions to her calculations, even her Corrected Opening Report does not consistently take into account these reduced numbers, as she continued to rely on the inaccurately inflated figures. (*Compare* Ex. 1 (Opening Report) at ¶¶ 278, 284, 287, 288, *with* Ex. 2 (Corrected Opening Report) at ¶¶ 278, 284, 287, 288.) The presence of inaccurate calculations and inconsistent corrections in Dr. Donovan's Corrected Opening Report not only undermines the reliability of her findings, but also introduces confusion for the trier of fact. It is imperative that expert testimony be clear, accurate, and based on sound methodology. However, Dr. Donovan's failure to perform calculations correctly, in addition to her faulty methodology, raises serious doubts as to the reliability and helpfulness of her analysis. Such inaccuracies only serve to obfuscate the issues at hand and impede the Court's ability to arrive at an informed decision.

2. Dr. Donovan's Analysis of the Breadth of the Claimed Concentration Ranges is Based on Arbitrary Assumptions and is Unrelated to the Breadth of the Disclosure

Dr. Donovan asserts that "the ordinarily skilled artisan would understand that an extremely large number of formulations are contemplated by the Asserted Claims" because the Asserted Claims are "directed to formulations having a large range of potential concentration for lidocaine (specifically, 0.5-7 mass %) including within the plaster (0.1 to 1 mg/cm^2)" and claim a "broad ratio for the concentration of dissolving agent in comparison to the lidocaine in the formulation (specifically, 0.5-5 mass % dissolving agent relative to 1 mass % lidocaine)." (Ex. 2 (Corrected

Opening Report) at ¶¶ 290, 294.) Dr. Donovan goes on to assert that the claimed ranges of lidocaine concentrations and ratios of dissolving agent to lidocaine encompass "75 lidocaine concentrations, the 320 lidocaine and dissolving agent combination concentrations, 45 different ratios between lidocaine and the dissolving agent, [and] 10 different amounts of lidocaine within the plaster[.]" (*Id.* at ¶ 294.) To reach these numbers Dr. Donovan arbitrarily breaks the claimed ranges down into discrete intervals. For example, Dr. Donovan asserts that a POSA would "at minimum understand that the claimed range covers discrete lidocaine concentrations differing by 0.1 mass %" but provides no explanation of why a POSA would have this understanding. (*Id.* at ¶ 291.) Dr. Donovan applies "this same analysis to the limitation defining the amount of lidocaine within the plaster (0.1 to 1 mg/cm^2)" without any explanation to support her bare assertion that a POSA would understand "there are 10 discrete lidocaine concentrations to choose from in the plaster." (*Id.*) Again, without any explanation Dr. Donovan concludes that "a person of ordinary skill in the art would understand that the claims would encompass approximately three hundred and twenty (320) possible concentrations for the dissolving agent used within 45 different dissolving agent: lidocaine proportions." (*See id.* at ¶¶ 291–92.)

This methodology is flawed. First, the use of 0.1 increments is arbitrary and inconsistent with how a POSA seeking to make and use the claimed patches would actually develop these formulations. (*See* Ex. 10 (Koleng Rebuttal Report) at ¶ 189.) As explained by Dr. Koleng and confirmed by Defendant's own expert, Dr. Prausnitz, a POSA "would test a far more limited set of concentrations, which would include concentrations at the high and low ends of the claimed concentration range (e.g., 0.5 and 7 mass % lidocaine) and a few in the middle to identify trends and identify the proper concentration for a particular application." (*Id.*) In his deposition, when asked how he would test a range of concentrations, Dr. Prausnitz confirmed Dr. Koleng's opinion

and contradicted Dr. Donovan's opinion, responding that one would test the low and high ends of the concentration and would test some increments between the low and high concentrations. (*See* Ex. 9 (Prausnitz Tr.) at 40:16-41:25.)[3] In fact, when asked during her deposition whether a POSA seeking to make and use the claimed patches would test lidocaine concentrations differing by 0.1 mass % across the entire range of 0.5 to 7 mass %, Dr. Donovan conceded that a POSA "might not do every single one of those concentrations." (*See* Ex. 8 (Donovan Tr.) at 242:8-9.) By her own testimony, Dr. Donavan's calculations based on "lidocaine concentrations differing by 0.1 mass %" intervals is incorrect and leads to unreliable results.

Furthermore, in relation to the enablement requirement, the breadth of the claims is analyzed in comparison to the breadth of the specification's disclosures—not as a function of the number of discrete embodiments the claims encompass. *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 684 (Fed. Cir. 2015) (holding that the time it takes to make a commercially viable embodiment is not determinative of non-enablement). Dr. Donovan's approach quantifies the breadth of the claims in a vacuum rather than in relation to the breadth of the specification's disclosure. As such Dr. Donovan's analysis is wholly uninformative with respect to whether the specification enables the full scope of the claimed range and should be excluded.

3. Dr. Donovan's Analysis Includes Unclaimed Limitations

In her assessment of the "potential formulations," Dr. Donovan introduces "the method of manufacture" as a variable, presupposing that "[a] skilled artisan would consider [either 5 or 2] methods of manufacture mentioned in the prior art (solvent casting, hot melt, aqueous emulsion

[3] The Prausnitz deposition transcript was marked Highly Confidential, but the parties conferred and the excerpted Exhibit 9 attached to this motion does not contain either parties' confidential information

coating, radiation curing, and calendaring)[.]" (Ex. 1 (Opening Report) at ¶¶ 300, 303, 306, 309, 312, 315, 318, 321, 324, 327, 330); (Ex. 2 (Corrected Opening Report) at ¶¶ 300, 303, 306, 309, 312, 315, 318, 321, 324, 327, 330.) Consequently, different methods of manufacture are integrated into her calculations, leading to a substantial inflation of the "potential formulations" by a factor of two or five.

However, this assumption is fundamentally flawed and provides further grounds for excluding Dr. Donovan's analysis regarding the breadth of the claims because none of the claims claim particular methods of manufacture. Section 112 mandates the enablement of "only the claimed invention," without extending to matters beyond the scope of the claims. *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020) . As described above, the Asserted Claims are directed towards a non-aqueous lidocaine patch composition and methods of using the patch composition—not to a method of manufacturing the patch. Yet, Dr. Donovan's assumptions and corresponding calculations deviate from this premise by incorporating the five distinct "methods of manufacture" into her calculations. Dr. Donvan's opinion is that a POSA would need to make all the claimed formulations using every available method of manufacture even though the claims don't contain any such manufacturing limitations. Dr. Donovan's flawed analysis seeks to improperly inflate and misrepresent the claim scope by relying on methods of manufacture that are not required by the claims. Such departure from the confines of the claims makes no sense and violates established principles of enablement, further warranting the exclusion of paragraphs 297-334 and Appendices D and E of Dr. Donovan's Opening and Corrected Opening Report, and paragraph 74 of her Reply and Corrected Reply Report. (Ex. 1 (Opening Report); Ex. 2 (Corrected Opening Report); Ex. 3 (Reply Report); Ex. 4 (Corrected Reply Report).)

V. CONCLUSION

Dr. Donovan's exemplary calculations, analysis of the breadth of the claimed concentration ranges, and her opinions relying thereon should be excluded from consideration in this case due to significant flaws in her methodology and analysis. Accordingly, the Court should exclude paragraphs 297-334 and Appendices D and E of her Opening and Corrected Opening Report, and paragraph 74 of her Reply and Corrected Reply Report. (Ex. 1 (Opening Report); Ex. 2 (Corrected Opening Report); Ex. 3 (Reply Report); Ex. 4 (Corrected Reply Report).)

Respectfully submitted,

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/s/ *John C. Carey*

John C. Carey (Fla. Bar No. 78379)
CAREY RODRIGUEZ LLP
1395 Brickell Avenue, Suite 700
Miami, Florida 33131
Tel: (305) 356-5455
jcarey@careyrodriguez.com

OF COUNSEL:

Sanya Sukduang
Jonathan R. Davies
Bonnie Fletcher Price
John Habibi
COOLEY LLP
1299 Pennsylvania Ave., NW, Ste. 700
Washington, DC 20004
Tel: (202) 842-7800
ssukduang@cooley.com
jdavies@cooley.com
bfletcherprice@cooley.com
jhabibi@cooley.com

Attorneys for Plaintiffs Scilex Pharmaceuticals Inc., ITOCHU CHEMICAL FRONTIER Corporation, Oishi Koseido Co., Ltd.

CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.1(a)(3), prior to this filing, Plaintiffs' counsel conferred with Defendant's counsel in good faith regarding the relief sought herein but was unable to reach a resolution.

/s/ *John C. Carey*
John C. Carey